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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,239	02/05/2007	Avidor Shulman	7056-X08-022	9066
27317	7590	01/05/2010	EXAMINER	
Fleit Gibbons Gutman Bongini & Bianco PL 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180				MERCIER, MELISSA S
1615		ART UNIT		PAPER NUMBER
01/05/2010		MAIL DATE		DELIVERY MODE
				PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/576,239	SHULMAN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	MELISSA S. MERCIER	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 October 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13-40 is/are pending in the application.  
 4a) Of the above claim(s) 13-24, 26-30 and 35 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 25, 31-34, 36-40 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicants Remarks and Amended Claims filed on October 14, 2009 is acknowledged. Claims 13-40 are pending in this application. Claims 13-24, 26-30, and 35 remain withdrawn from consideration. Applicant has presented new claims 37-40, therefore claims 25, 31-34, and 36-40 are now under prosecution in this application.

### **Withdrawn Rejections**

#### ***Claim Rejections - 35 USC § 112***

The rejection of Claims 25, 31-34 and 36 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of Applicants amendment to the claims to recite remove the phrase “oils mimicking the triglyceride composition of human are mother’s milk fat, or a food article comprising the same”.

The rejection of claims 25, 31-34, and 36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicants amendments to claims 25 and 32 to remove the limit within a limit language and the term including, respectfully.

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 25, 31-34, and 36 under 35 U.S.C. 102(b) as being anticipated by Kennedy et al. (Double blind, randomized trial of a synthetic

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triacylglycerol in formula fed term infants: effects on stool biochemistry, stool characteristics, and bone mineralization) has been withdrawn in view of Applicants arguments regarding the lack of a teaching of the fatty acid moieties at the sn-1 and sn-3 positions and Applicants amendment to limit the patient population to children and adults.

### ***Newly Applied Rejections***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25, 31-34, and 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites "a method of enhancing dietary calcium absorption, bone formation and bone mass maximization" by administered a lipid, however, the claim also recites "said lipid does not inhibit calcium absorption, and/or enhances calcium absorption and intake". It is unclear how the method can accomplish the intended result if the only component being administered does not perform the intended function. Clarification is requested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 32, 34, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by FoodIngredientsFirst article, Enzymotec launches InFat-perfect fat for infant formulas, available online April 7, 2003).

The article discloses the use of InFat, which the specification discloses is the lipid component of the instant invention. The article further discloses that incorporating InFat into infant formulas will increase a baby's energy and calcium intake. It is noted that Applicant has amended the claims to recite a child or adult, however, it is the position of the Examiner that a child would encompass an infant. Applicant has not defined an exact age range to define each grouping separately to distinguish them.

Claims 25, 32, 34, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Spurgeon et al, hereinafter referred to as Spurgeon, (An investigation of the general, reproductive and postnatal developmental toxicity of Betapol, a human milk fat equivalent; available online August 2, 2003).

Spurgeon discloses the use of Betapol in infant foods as well as foods in general (abstract). Applicant has indicated that Betapol is a commercially available product meeting the structural requirements of the instantly claimed lipid (pages 10 and 15 of the instant specification).

Spurgeon discloses the use of Betapol provides enhanced fat absorption and calcium retention.

Regarding claims 34 and 36, the claims recite functional properties of the lipid component. Since Spurgeon discloses the same lipid, it would necessarily also perform the same functional properties.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25, 31-34, and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spurgeon et al, hereinafter referred to as Spurgeon, (An investigation of the general, reproductive and postnatal developmental toxicity of Betapol, a human milk fat equivalent; available online August 2, 2003) in view of Kennedy et al. (Double blind, randomized trial of a synthetic triacylglycerol in formula fed term infants: effects on stool biochemistry, stool characteristics, and bone mineralization).

The teachings of Spurgeon has been discussed above and applied in the same manner.

Spurgeon does not disclose what additional components are contained within the food product. It is noted that Applicant has amended the claims to recite a child or adult, however, it is the position of the Examiner that a child would encompass an infant. Applicant has not defined an exact age range to define each grouping separately to distinguish them.

Regarding claims 34 and 36, the claims recite functional properties of the lipid component. Since Spurgeon discloses the same lipid, it would necessarily also perform the same functional properties.

Regarding claims 38-40, while Spurgeon does not specifically disclose the incorporation of Betapol into pastries, breads, and infant food which is not formula, it would have been obvious to the skilled artisan to incorporate it into said articles based on the teachings of Spurgeon as acceptable for use in food articles in general. It would have been obvious to a skilled artisan to try to incorporate it into food articles in order to obtain the same beneficial properties which are seen in the infant formula.

Kennedy discloses an infant formula comprising triacylglycerols with high sn-2 palmitate on the glycerol backbone and calcium, among other vitamins, was administered to term infants and showed an increase in calcium absorption and greater skeletal mineral deposition. The formula further comprised proteins, carbohydrates, and vitamins which are considered to be edible additives, thereby meeting the limitation of claim 31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the lipid component of Spurgeon in the infant formula of Kennedy since Spurgeon discloses the Betapol provides enhanced fat absorption and calcium retention.

Claims 25, 31-34, 36-37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over FoodIngredientsFirst article, Enzymotec launches InFat-perfect fat for

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infant formulas, available online April 7, 2003) in view of Kennedy et al. (Double blind, randomized trial of a synthetic triacylglycerol in formula fed term infants: effects on stool biochemistry, stool characteristics, and bone mineralization).

The FoodIngredientFirst article has been discussed above and applied in the same manner.

The FoodIngredientFirst article does not disclose what additional components are contained within the food product. It is noted that Applicant has amended the claims to recite a child or adult, however, it is the position of the Examiner that a child would encompass an infant. Applicant has not defined an exact age range to define each grouping separately to distinguish them.

Kennedy discloses an infant formula comprising triacylglycerols with high sn-2 palmitate on the glycerol backbone and calcium, among other vitamins, was administered to term infants and showed an increase in calcium absorption and greater skeletal mineral deposition. The formula further comprised proteins, carbohydrates, and vitamins which are considered to be edible additives, thereby meeting the limitation of claim 31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the lipid component InFat in the infant formula of Kennedy since it is disclosed that increase a babies energy and calcium intake.

***Conclusion***

**Due to the new grounds of rejection presented in this office action, this action is made Non-Final.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner, Art Unit 1615